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Substitute for form 1449A/PTO

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INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

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Sheet

1

of

10

Application Number

10/585,611

Filing Date

11-Jul-2006

First Named Inventor

SIEGEL, Steven

Art Unit

1615

Examiner Name

Attorney Docket Number

P-7562-US

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
A	US-4,883,666		11-28-1989	Sabel, et al.	
B	US-5,601,835		02-11-1997	Sabel, et al.	
C	US-6,130,200		10-10-2000	Brodbeck, et al.	
D	US-6,166,173		12-26-2000	Mao, et al.	
E	US-5,629,008		05-13-1997	Lee	
F	US-5,665,428		09-09-1997	Cha, et al.	
G	US-5,817,343		10-06-98	Burke	
H	US-5,871,778		02-16-1999	Kino, et al.	
I	US-4,989,463		11-23-1999	Tracy, et al.	
J	US-6,004,573		12-21-1999	Rathi, et al.	
K	US-6,117,949		09-12-2000	Rathi, et al.	
L	US-6,143,314		11-07-2000	Chandrashekhar	
M	US-6,201,072		03-13-2001	Rathi, et al.	
N	US-5,770,231		06-23-1998	Jean Mesens, Wechelderzande	
O	US-6,544,559		04-08-2003	Jean Mesens, Wechelderzande	
P	US-6,368,362		04-09-2002	Ronald Pedemonte, et al.	
Q	US-6,110,921		08-29-2000	Jean Mesens, Wechelderzande	
R	US-5,965,168		10-12-1999	Jean Mesens, Wechelderzande	
S	US-6,803,055		10-12-2004	Jean Mesens, Wechelderzande	
T	US-5,792,477		08-11-1998	Michael Rickey, et al.	
U	US-5,654,008		08-05-1997	J. Michael Ramstack	
V	US-2002-0179096A1		12-05-2002	Siegel, et al.	
W	US 4,351,337		09-28-1982	Sidman	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
X	WO 94/10982		05-26-1994	Kino, et al.		<input type="checkbox"/>
Y	EP 669128		01-05-2000	Kino, et al.		<input type="checkbox"/>

Examiner Signature	Date Considered
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The collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449B/PTO				Complete if Known	
				Application Number	10/585,611
				Filing Date	11-Jul-2006
				First Named Inventor	SIEGEL, Steven
				Art Unit	1615
(use as many sheets as necessary)				Examiner Name	
Sheet	2	of	10	Attorney Docket Number	P-7562-US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	1	ADAMS CE, Fenton MK, Quraishi S, David AS (2001) Systematic meta-review of depot antipsychotic drugs for people with schizophrenia. Br J Psychiatry 179:290-299.	<input type="checkbox"/>
	2	ANDERSON, et al. (1997) Biodegradation and biocompatibility of PLA and PLGA microspheres. Adv Drug Delivery Rev 28:5-24	<input type="checkbox"/>
	3	AYUSO-GUTIERREZ, et al. (1997) Factors influencing relapse in the long-term course of schizophrenia. Schizophr Res 28:199-206.	<input type="checkbox"/>
	4	BENELLI, et al. (1998) Clonazepam microencapsulation in poly-D, L-lactide-co-glycolide microspheres. J. Micorenseapsulation 15(4):431-443.	<input type="checkbox"/>
	5	BOCCUZZI et al. (2001) Utilization of oral hypoglycemic agents in a drug-insured U.S. population. Diabetes Care. Aug;24(8):1411-5.	<input type="checkbox"/>
	6	BUCKLAND, et al. (1993) Both splicing variants of the dopamine D2 receptor mRNA are up-regulated by antipsychotic drugs. Neurosci Lett 150:25-28.	<input type="checkbox"/>
	7	CHEN, et al. (2005) Microarray analysis of differentially expressed genes in rat frontal cortex under chronic risperidone treatment. Neuropsychopharmacology 30:268-277.	<input type="checkbox"/>
	8	CHENG, et al. (1998) A poly (D,L-lactide-co-glycolide) microsphere depot system for delivery of haloperidol. J. Controlled Release 55(2-3):203-212.	<input type="checkbox"/>
	9	CHENG, et al. (2000) Schizophrenia and Drug Delivery Systems. J Drug Targeting 8(2):107-117.	<input type="checkbox"/>
	10	CHUI et al. (2003) Association between adherence to diuretic therapy and health care utilization in patients with heart failure. Pharmacotherapy. Mar;23(3):326-32.	<input type="checkbox"/>
	11	CORRISS, et al. (1999) Interactive risk factors for treatment adherence in a chronic psychotic disorders population. Psychiatry Res 89:269-274.	<input type="checkbox"/>

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	12	CSERNANSKY (2003) Treatment of schizophrenia: preventing the progression of disease. Psychiatr Clin North Am 26:367-379.			<input type="checkbox"/>
	13	DASH, et al. (1998) Therapeutic applications of implantable drug delivery systems. J Pharmacol Toxicol Methods 40:1-12.			<input type="checkbox"/>
	14	DAVIS, et al. (2003) A meta-analysis of the efficacy of second-generation antipsychotics. Arch Gen Psychiatry 60:553-564.			<input type="checkbox"/>
	15	DORPH-PETERSEN, et al. (2004) Stereological analysis of the mediodorsal thalamic nucleus in schizophrenia: volume, neuron number, and cell types. J Comp Neurol 472:449-462.			<input type="checkbox"/>
	16	ELMER, et al. (1996) Cocaine cross-sensitization to dopamine uptake inhibitors: unique effects of GBR12909. Pharmacol Biochem Behav 53:911-918.			<input type="checkbox"/>
	17	FISCHEL-GHODSIAN, et al. (1993) Analysis of drug release kinetics from degradable polymeric devices. J Drug Target 1(1):51-57.			<input type="checkbox"/>
	18	FOSS, et al. (2004) Development of acrylic-based copolymers for oral insulin delivery. Eur J Pharm Biopharm 57:163-169.			<input type="checkbox"/>
	19	FOSTER AND GOA (1998) Risperidone. A pharmacoeconomic review of its use in schizophrenia. Pharmacoeconomics. Jul;14(1):97-133.			<input type="checkbox"/>
	20	FRANK, et al. (2005) Controlled release from bioerodible polymers: effect of drug type and polymer composition. J Controlled Release 102:333-344.			<input type="checkbox"/>
	21	FREIBERG AND ZHU (2004) Polymer microspheres for controlled drug release. Int J Pharm. Sep 10;282(1-2):1-18			<input type="checkbox"/>
	22	GANDER, et al. (2001) Polymers as a platform for drug delivery: Reviewing our current portfolio on poly(lactide-co-glycolide) (PLGA) microspheres. CHIMIA 55:212-217.			<input type="checkbox"/>

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	23	GEDDES, et al. (2000) Atypical antipsychotics in the treatment of schizophrenia: systematic overview and meta-regression analysis. BMJ 321:1371-1376.			<input type="checkbox"/>
	24	GOSS, et al. (1991) Haloperidol treatment increases D2 dopamine receptor protein independently of RNA levels in mice. Life Sci 48:1015-1022.			<input type="checkbox"/>
	25	GRAYSON, et al. (2005) Size and temperature effects on poly(lactic-co-glycolic acid) degradation and microreservoir device performance, Biomaterials 26:2137-2145.			<input type="checkbox"/>
	26	HARRISON AND GOA (2004) Long-acting risperidone: a review of its use in schizophrenia. CNS Drugs.; 18(2):113-32.			<input type="checkbox"/>
	27	HELLER, (1979) Controlled drug release by polymer dissolution. II: Enzyme-mediated delivery device. J Pharm Sci. 68(7):919-21.			<input type="checkbox"/>
	28	HIGUCHI T., (1961) Rate of release of medicaments from ointment bases containing drugs in suspensions. J. Pharm. Sci. 50:874-875.			<input type="checkbox"/>
	30	HOLY, et al. (2001) Optimizing the sterilization of PLGA scaffolds for use in tissue engineering. Biomaterials 22:25-31.			<input type="checkbox"/>
	31	HUSSAIN (2001) Fluorometric method for the simultaneous quantitation of differently-sized nanoparticles in rodent tissue. Int J Pharm 214:55-61.			<input type="checkbox"/>
	32	IRANI, et al. (2004) Patient attitudes towards surgically implantable, long-term delivery of psychiatric medicine. Neuropsychopharmacology 29:960-968.			<input type="checkbox"/>
	33	JAIN, et al. (2000) Controlled delivery of drugs from a novel injectable in situ formed biodegradable PLGA microsphere system. J Microencapsulation 17(3):343-62.			<input type="checkbox"/>

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Application Number	10/585,611
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				First Named Inventor	SIEGEL, Steven
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	34	JEONG, et al. (2003) Preparation of poly(DL-lactide-co-glycolide) microspheres encapsulating all-trans retinoic acid. Int J Pharm 259:79-91.			<input type="checkbox"/>
	35	KANE (1999) Olanzapine in the long-term treatment of schizophrenia. Br J Psychiatry Suppl: (37) 26-29.			<input type="checkbox"/>
	36	KANE, et al. (1998) Guidelines for depot antipsychotic treatment in schizophrenia. European Neuropsychopharmacology Consensus Conference in Siena, Italy. Eur Neuropsychopharmacol 8:55-66.			<input type="checkbox"/>
	37	KANE, et al. (2002) Efficacy and safety of aripiprazole and haloperidol versus placebo in patients with schizophrenia and schizoaffective disorder. J Clin Psychiatry 63:763-771.			<input type="checkbox"/>
	38	KAROW, et al. (2002) Subjective well-being and quality of life under atypical antipsychotic treatment. Psychopharmacology (Berl) 162:3-10.			<input type="checkbox"/>
	39	KEEFE, et al. (2004) Comparative effect of atypical and conventional antipsychotic drugs on neurocognition in first-episode psychosis: a randomized, double-blind trial of olanzapine versus low doses of haloperidol. Am J Psychiatry 161:985-995.			<input type="checkbox"/>
	40	KEITH, et al. (2003) Partial compliance and patient consequences in schizophrenia: our patients can do better. J Clin Psychiatry 64:1308-1315.			<input type="checkbox"/>
	41	KITCHELL, et al. (1985) Poly (lactic/glycolic acid) biodegradable drug-polymer matrix systems. Methods Enzymol. 112:436-48.			<input type="checkbox"/>
	42	KLAVON, et al. (1990) Insertion site complications during the first year of NORPLANT use. Contraception 41:27-37.			<input type="checkbox"/>
	43	KNABLE, et al. (1997) Extrapyramidal side effects with risperidone and haloperidol at comparable D2 receptor occupancy levels. Psychiatry Res 75:91-101.			<input type="checkbox"/>
	44	KNEGTERING, et al. (2005) Predominant role of the 9-hydroxy metabolite of risperidone in elevating blood prolactin levels. Am J Psychiatry 162:1010-1012.			<input type="checkbox"/>

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	45	KOHLER, et al. (1994) A new animal model of dopamine supersensitivity using s.c. implantation of haloperidol releasing polymers. Neuroscience Letters 170(1):99-102		<input type="checkbox"/>
	46	KULKARNI, et al. (1971) Biodegradable poly(lactic acid) polymers. 5(3):169-81.		<input type="checkbox"/>
	47	KUSUMI, et al. (2000) Differential effects of subchronic treatments with atypical antipsychotic drugs on dopamine D2 and serotonin 5-HT2A receptors in the rat brain. J Neural Transm 107:295-302.		<input type="checkbox"/>
	48	LAMBERT, et al. (2003) Pharmacological approaches to the management of schizophrenia. Med J Aust 178 Suppl: S57-61.		<input type="checkbox"/>
	49	LAROBINA, et al. (2002) Mechanistic understanding of degradation in bioerodible polymers for drug delivery. AIChE J 48:2960-2970.		<input type="checkbox"/>
	50	LELAS, et al. (2004) Anxiolytic-like effects of the corticotropin-releasing factor1 (CRF1) antagonist DMP904 [4-(3-pentylamino)-2,7-dimethyl-8-(2-methyl-4-methoxyphenyl)-pyrazolo-[1,5-a]pyrimidine] administered acutely or chronically at doses occupying central CRF1 receptors in rats. J Pharmacol Exp Ther 309:293-302.		<input type="checkbox"/>
	51	LEWIS, et al. (2001a) Lamina-specific deficits in parvalbumin-immunoreactive varicosities in the prefrontal cortex of subjects with schizophrenia: evidence for fewer projections from the thalamus. Am J Psychiatry 158:1411-1422.		<input type="checkbox"/>
	52	LEWIS, et al. (2001b) Service use and costs of treating schizophrenia with atypical antipsychotics. J Clin Psychiatry 62:749-756.		<input type="checkbox"/>
	53	LEYSEN, et al. (1994) Risperidone: a novel antipsychotic with balanced serotonin-dopamine antagonism, receptor occupancy profile, and pharmacologic activity. J Clin Psychiatry 55 Suppl:5-12.		<input type="checkbox"/>
	54	LI, et al. (1996) Hydrolytic degradation of poly (D,L-lactic acid) in the presence of caffeine base. J. Control. Release 40:41-53.		<input type="checkbox"/>

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	55	LILLY, et al. (1998) A physiologically based pharmacokinetic description of the oral uptake, tissue dosimetry, and rates of metabolism of bromodichloromethane in the male rat. Toxicol Appl Pharmacol 150:205-217.			<input type="checkbox"/>
	56	LINHARDT (1989) "Biodegradable Polymers for Controlled Release of Drugs" Controlled Release of Drugs, Rosoff, Ed., New York: VCH Publishers, Chapter 2, p. 53-83.			<input type="checkbox"/>
	57	LU ET AL. (2000) In vitro and in vivo degradation of porous poly(DL-lactic-co-glycolic acid) foams. Biomaterials. Sep; 21(18):1837-45.			<input type="checkbox"/>
	58	MARTIN, et al. (2003) Clinical experience with the long-acting injectable formulation of the atypical antipsychotic, risperidone. Curr Med Res Opin 19:298-305.			<input type="checkbox"/>
	59	MCCOMBS, et al. (1999) Use patterns for antipsychotic medications in medicaid patients with schizophrenia. J Clin Psychiatry 60 Suppl 19:5-11; discussion 12-13.			<input type="checkbox"/>
	60	MCQUADE, et al. (2004) A comparison of weight change during treatment with olanzapine or aripiprazole: results from a randomized, double-blind study. J Clin Psychiatry 65 Suppl 18:47-56.			<input type="checkbox"/>
	61	MELTZER (1995) The role of serotonin in schizophrenia and the place of serotonin-dopamine antagonist antipsychotics. J Clin Psychopharmacol 15:2S-3S.			<input type="checkbox"/>
	62	MENZIN, et al. (2003) Treatment adherence associated with conventional and atypical antipsychotics in a large state medicaid program. Psychiatr Serv 54:719-723.			<input type="checkbox"/>
	63	METZGER, et al. "Pharmacokinetic and behavioral characterization of a long-term antipsychotic delivery system in rodents and rabbits" Psychopharmacology (Berl). 2007 Feb; 190(2):201-11.			<input type="checkbox"/>
	64	MILLER-CHOU, et al. (2003) A reviews of polymer dissolution. Progress Pol Sci 28:1223-1270.			<input type="checkbox"/>
	65	NARASIMHAN, et al. (1997) Molecular analysis of drug delivery systems controlled by dissolution of the polymer carrier. J Pharma Sci 86:297-304.			<input type="checkbox"/>

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				Application Number	10/585,611
				Filing Date	11-Jul-2006
				First Named Inventor	SIEGEL, Steven
				Art Unit	1615
(use as many sheets as necessary)				Examiner Name	
Sheet	8	of	10	Attorney Docket Number	P-7562-US

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	66	NASRALLAH, et al. (2002) Efficacy, safety, and tolerability of quetiapine in patients with schizophrenia. J Clin Psychiatry 63 Suppl 13:12-20.		<input type="checkbox"/>
	67	NASRALLAH, et al. (2004) Atypical antipsychotics and metabolic dysregulation: evaluating the risk/benefit equation and improving the standard of care. J Clin Psychopharmacol 24:S7-14.		<input type="checkbox"/>
	68	NATSUGOE, et al. (1960) Controlled Release of Cisplatin Incorporated into Biodegradable Poly-D, L-Lactic Acid. Anticancer Research 17(3C):1957-60.		<input type="checkbox"/>
	69	NYBERG, et al. (1996) Positron emission tomography of in-vivo binding characteristics of atypical antipsychotic drugs. Review of D2 and 5-HT2 receptor occupancy studies and clinical response. Br J Psychiatry Suppl:40-44.		<input type="checkbox"/>
	70	OKADA, et al. (1995) Biodegradable microspheres in drug delivery. Crit Rev Ther Drug Carrier Syst 12:1-99.		<input type="checkbox"/>
	71	PANYAM, et al. (2003) Biodegradable nanoparticles for drug and gene delivery to cells and tissue. Adv Drug Delivery Rev 55:329-347.		<input type="checkbox"/>
	72	RAMASWAMY, et al. (2004) Aripiprazole possibly worsens psychosis. Int Clin Psychopharmacol 19:45-48.		<input type="checkbox"/>
	73	REEVES, et al. (2004) Worsening schizoaffective disorder with aripiprazole. Am J Psychiatry 161:1308.		<input type="checkbox"/>
	74	REUSS, et al. (2001) Atypical neuroleptic drugs downregulate dopamine sensitivity in rat cortical and striatal astrocytes. Mol Cell Neurosci 18:197-209.		<input type="checkbox"/>
	75	ROBINSON, et al. (2002) Predictors of medication discontinuation by patients with first-episode schizophrenia and schizoaffective disorder. Schizophr Res 57:209-219.		<input type="checkbox"/>
	76	RON, et al. (1991) "Erodible Systems" Treatise on Cont. Drug Del. 199-217.		<input type="checkbox"/>

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	77	ROSKOS, et al. (1997) "Degradable controlled release systems useful for protein delivery" in Protein Delivery: Physical Systems, Sanders and Hendren eds., Plenum press, New York, Chapter 2, 45-92.			<input type="checkbox"/>
	78	SABEL, et al. (1990) Levodopa delivery from controlled-release polymer matrix: delivery of more than 600 days in vitro and 225 days of elevated plasma levels after subcutaneous implantation in rats. J Pharmacol Exp Ther 255:914-922.			<input type="checkbox"/>
	79	SARMA, et al. (1995) Neurovascular injury during removal of levonorgestrel implants. Am J Obstet Gynecol 172:120-121.			<input type="checkbox"/>
	80	SCHOTTE, et al. (1996) Risperidone compared with new and reference antipsychotic drugs: in vitro and in vivo receptor binding. Psychopharmacology (Berl) 124:57-73.			<input type="checkbox"/>
	81	SEEMAN MV (2001) Clinical trials in psychiatry: do results apply to practice? Can J Psychiatry 46:352-355.			<input type="checkbox"/>
	82	SHARMA, et al. (2003) Cognitive function in schizophrenia. Deficits, functional consequences, and future treatment. Psychiatr Clin North Am 26:25-40.			<input type="checkbox"/>
	83	SIEGEL (2007) Extended release drug delivery strategies in psychiatry: Theory to practice. Psychiatry.			<input type="checkbox"/>
	84	SIEGEL, et al. (2002) Surgically implantable long-term antipsychotic delivery systems for the treatment of schizophrenia. Neuropsychopharmacology 26:817-823.			<input type="checkbox"/>
	85	SIEGEL, et al. (2006) Effect of drug type on the degradation rate of PLGA Matrices. Eur J Pharm Biopharm. 64(3):287-93.			<input type="checkbox"/>
	86	SIEPMANN, et al. (2001) Mathematical modeling of bioerodible, polymeric drug delivery systems. Adv Drug Delivery Rev 48:229-247.			<input type="checkbox"/>
	87	SIMPSON, et al. (2004) Randomized, controlled, double-blind multicenter comparison of the efficacy and tolerability of ziprasidone and olanzapine in acutely ill inpatients with schizophrenia or schizoaffective disorder. Am J Psychiatry 161:1837-1847.			<input type="checkbox"/>
	88	STRAKOWSKI, et al. (2003) Atypical antipsychotics in the treatment of bipolar disorder. Expert Opin Pharmacother 4:751-760.			<input type="checkbox"/>
	89	SUNG, et al. (1998) Controlled release of nalbuphine prodrugs from biodegradable polymeric matrices: influence of prodrug hydrophilicity and polymer composition. Int. J. Pharm. 172:17-25.			<input type="checkbox"/>
	90	SVARSTAD, et al. (2001) Using drug claims data to assess the relationship of medication adherence with hospitalization and costs. Psychiatr Serv 52:805-811.			<input type="checkbox"/>

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	91	SWAINSTON HARRISON, et al. (2004) Aripiprazole: a review of its use in schizophrenia and schizoaffective disorder. Drugs 64:1715-1736.			<input type="checkbox"/>
	92	SWERDLOW, et al. (1994) Assessing the validity of an animal model of deficient sensorimotor gating in schizophrenic patients. Arch Gen Psychiatry 51:139-154.			<input type="checkbox"/>
	93	TARAZI, et al. (2002) Long-term effects of olanzapine, risperidone, and quetiapine on serotonin 1A, 2A and 2C receptors in rat forebrain regions. Psychopharmacology (Berl) 161:263-270.			<input type="checkbox"/>
	94	TEICH (2003) Side effects of ziprasidone. Am J Psychiatry 160:1355-1356.			<input type="checkbox"/>
	95	VELLIGAN, et al. (2003) Psychopharmacology: perspectives on medication adherence and atypical antipsychotic medications. Psychiatr Serv 54:665-667.			<input type="checkbox"/>
	96	VISCO, et al. (1999) Observed patient compliance with a structured outpatient bladder retraining program. Am J Obstet Gynecol 181:1392-1394.			<input type="checkbox"/>
	97	WADA, et al. (1991) In vitro evaluation of sustained drug release from biodegradable elastomer. Pharm Res. 8(10):1292-1296.			<input type="checkbox"/>
	98	WANG, et al. (2000) Synthesis, characterization, biodegradation, and drug delivery application of biodegradable lactic/glycolic acid polymers: I. Synthesis and characterization. J Biomater Sci Polym Ed. 11(3):301-18.			<input type="checkbox"/>
	99	YASUI-FURUKORI, et al. (2001) Different enantioselective 9-hydroxylation of risperidone by the two human CYP2D6 and CYP3A4 enzymes. Drug Metab Dispos 29:1263-1268.			<input type="checkbox"/>
	100	ZHENG, et al. (1998) High-performance liquid chromatography-mass spectrometry-mass spectrometry analysis of morphine and morphine metabolites and its application to a pharmacokinetic study in male Sprague-Dawley rats. J Pharm Biomed Anal 16:971-980.			<input type="checkbox"/>
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